K061051
Page 1 of 3

JUN 13 2006

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.87 (h).

Submitter:

Sicel Technologies, Inc.
3800 Gateway Centre Blvd.
Suite 308
Morrisville, NC 27560

Contact: Tammy B. Carrea, Director Regulatory Affairs
Phone: (919) 465-2236 ext. 225
Fax: (919) 465-0153

Prepared: April 14, 2006

Common or Usual Name:	Patient Radiation Dosimeter
Proprietary Name:	DVS, Dose Verification System
Classification Name:	System, Radiation Therapy, Charged-Particle, Medical
Manufactured By:	Sicel Technologies, Inc. 3800 Gateway Centre Blvd. Suite 308 Morrisville, NC 27560 Phone: (919) 465-2236 Fax: (919) 465-0153

K061051
Page 2 of 3

Predicate Device(s):

K061051

Sicel Technologies, Inc.
K052118
DVS, Dose Verification System

Device Description:

The DVS, Dose Verification System consists of four sub-systems: the DVS Implantable Dosimeter for measuring radiation dose *in vivo*, the DVS Insertion Tool for implanting the dosimeter during percutaneous procedures, the DVS Reader System (Wand and Base Station) for powering the dosimeter and providing a user interface when taking dose measurements, and the DVS Data System (Plan and Review Software and Dosimetery Database) for storing and reporting patient data and for storing dosimeter information. The dosimeters use a MOSFET, Metal Oxide Semiconductor Field Effect Transistor, as a sensing mechanism. The dosimeter is factory calibrated and powered by the Reader Wand utilizing electromagnetic energy. The dosimeter contains a transmitter, to transmit threshold voltage readings to the reader. It is radioopaque and thus registers on computed tomography scans as a point of interest whereby a point dose may be determined. Patients are implanted prior to radiotherapy. Information on the patient's therapy, dose planning, point dose at the dosimeter, dosimeter serial number and calibration files are entered into the Plan and Review software and stored in the Dosimetry Database. At each therapy fraction the dosimeter is read pre- and post-therapy using the Reader Wand and Base Station. This translates into a daily fractional dose. The patient's daily and cumulative dose may be reviewed via the Plan and Review software. Because the Plan and Review software and Dosimetry Database are designed to be stored on a server, multiple users may be logged into the system at any one time. Reports on the patient's daily and cumulative dose history may be printed using the Plan and Review software.

Indication for Use:

The DVS (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

The DVS system is specifically indicated for breast and prostate cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.

K061051
Page 3 of 3

Comparison with Predicate Device: K061051

The intended use of this SICEL DVS is identical to the predicate device, the DVS Dose Verification System.

The indications for use of the SICEL DVS also are the same as the predicate device except for the additional indication for prostate cancer.

The technological features of the SICEL DVS are the same as the predicate including the use of MOSFET technology, the calibration method, dose range, energy sources measured, and dose management software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUN 13 2006

Ms. Tammy B. Carrea
Director, Regulatory Affairs
Sicel Technologies, Inc.
3800 Gateway Centre Boulevard, Suite 308
MORRISVILLE NC 27560

Re: K061051
Trade/Device Name: DVS, Dose Verification System
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: April 14, 2006
Received: April 17, 2006

Dear Ms. Carrea:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K061051

Device Name: DVS, Dose Verification System

Indications for Use:

Intended Use

The DVS (Dose Verification System) is intended for use in radiation therapy to verify treatment planning and radiation dose to tissue and organs in or near the irradiated areas of a patient.

Indications for Use

The DVS system is specifically indicated for breast and prostate cancer to measure photon beam therapy and as an adjunct to treatment planning to permit measurement of the *in vivo* radiation dose received at the tumor periphery, tumor bed and/or surrounding normal tissues for validation of the prescribed dose.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061051